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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,541	STINSON, JONATHAN S.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 68-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 68-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed December 14, 2004 have been fully considered but they are not persuasive.

Applicant has argued that the Ryan reference (US 5,830,217) does not disclose a tip member which extends distally beyond the distal extremity of the tubular body. The examiner disagrees. Ryan does indeed disclose a tip member (15), see fig.3, which extends distally beyond a distal extremity of the tubular body (3). Ryan discloses a perforation in the tip member, col.4, lines 40-47, the perforation is for the guidewire (4), and permissible for the catheter and balloon. Although the balloon catheter is shown in figure 3 to extend distal of the tip, Ryan discloses that it not nessasarily extend that far, Ryan discloses that the balloon (2) and catheter (3) *may permissibly* extend through the perforation in the tip (15), therefore, do not nessarily have to extend distally that far, and in some cases do not (col.4, lines 40-47).

Applicant has also argued that Ryan does not disclose a tip member which does not hinder deployment of the occlusion device. The examiner disagrees. Ryan discloses a tip member (15), which barely, if at all covers an occlusion device (1), see figure 3. The occlusion device is disclosed to expand even if the tip (15) does not dissolve, col.8, lines 20-27. Also, Ryan clearly discloses non-hindered deployment of the occlusion device, col.6, lines 13-17, and that the occlusion device may be deployed even before the tip dissolves, col.8, lines 20-27; col.6, lines 19-23. In addition, when using a balloon expandable stent, before the tip dissolves, the tip does not at all hinder deployment, since deployment *requires expansion of the balloon*. Also, in

the embodiment in figure 4, the tip is underneath of the stent and also would not hinder deployment.

Applicant has in addition argued that Ryan does not disclose a tip member which remains fixedly attached to the tubular body during the entire dissolution or degradation process. The examiner disagrees. Ryan discloses a tip member which may completely, partly, or not at all dissolve, therefore, some of the tip will remain on the tubular body at all times, col.6, lines 19-23; col.8, lines 18-27. And also, since the balloon must expand the stent, the tip is *configured* to let dissolve completely, before the surgeon begins to expand the balloon.

Applicant has argued that the Roberts reference (US 5,603,698) does not discloses a tip which is fixedly secured to a tubular body. The examiner disagrees. Roberts discloses a tip 26 which is mounted on the tubular body 4, thus secured to the tubular body by a friction fit (col.5, lines 65-67). Also, the tip 26 is further secured by an outer sheath 22 and stop 33. The tip 26 is fixedly secured until and if at all a surgeon forcingly removes it. Thus, Roberts tip is fixedly secured to the tubular body, and *configured to* stay so.

Applicant has also argued the tip is not configured to remain fixedly secured to the tubular body during bioabsorption or dissolution. The examiner disagrees. The tip 26 is fixedly secured to the tubular body 4 until the surgeon forcingly removes it (see above). Therefore, unless force is applied, the tip 26 will remain on the tubular body 4, thus it is *configured* to remain on the body. Also, Roberts even discloses that the tip is *selectively* dislodgeable, and *can*, or *may* be removed, or is remov*able* (col.1, lines 58-61; col.2, lines 60-61; col.4, lines 5-6; col.5 line 67-col.6 line 1), therefore, it need not be removed and may remain secured. Also, removal of the tip 26 from the body 4, is a method step, and is irrelevant to applicants claims.

The applicants claims are product claims, claiming a tip which is capable of remaining on the tubular body, which has the same structure and is the same end product of Roberts, a tip fixedly secured and configured to remain so throughout dissolution or bioabsorption.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33 and 68-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Ryan (US 5,830,217, cited in previous office action). Referring to claim 33, Ryan discloses an occlusion device delivery system comprising a tubular body (3) including a distal portion (area of 3 near balloon 2) including a distal extremity (5, see fig.1; left end of 3 in figure 3), a releasably deployable occlusion device (1) positioned on the distal portion of the tubular body (3), and a distal tip member (15) fixedly secured to the distal portion of the tubular body (3), wherein the distal tip member (15) distally extends beyond the distal extremity of the tubular body (Ryan discloses a distal extremity of the catheter 2, to be extremity 5, see location of 5 in fig.1, and the tip material 15 of the embodiment in fig.3, is shown to cover an area where extremity 5 is located; tip 15 is located at the extremity 5 of the tubular catheter 3 and tip 15 is disclosed to have an aperture allowing *only* the guidewire to pass through, *not* the catheter

extremity, see col.4, lines 42-46; Ryan discloses it is *permissible* for the *balloon* to peak out of the guidewire lumen, however *not* the extremity of the catheter, even if the catheter extremity 5 were to extend distally of the aperture, it would only be *permissible* to do so, and not required, therefore, tip 15 extends *beyond* the extremity of the catheter 5), the distal tip member (15) including at least a partially bioabsorbable or dissolvable material (col.4, lines 47-59).

Referring to claim 80, Ryan discloses an occlusion device delivery system comprising a tubular body (3) including a distal portion (area of 3 near balloon 2), a releasably deployable occlusion device (1) positioned on the distal portion (area near 2) of the tubular body (3), and a distal tip member (15) fixedly secured to the distal portion of the tubular body (area of 3 near 2), the distal tip member (15) configured to undergo bioabsorption or dissolution when the distal tip member (15) is placed in vivo (col.4, lines 47-59), wherein the distal tip member (15) is *configured* to remain fixedly secured to the distal portion of the tubular body (area of 3 near 2) during the entire bioabsorption or dissolution process, wherein the distal tip member (15) does not hinder deployment of occlusion device prior to undergoing bioabsorption or dissolution (tip (15) does not hinder deployment, see, col.6, lines 15-17; especially since the majority of the occlusion device (1) is not covered by the tip (15), and therefore will deploy no matter what anyways, in addition, when a balloon expandable occlusion device is used, the occlusion device (1) requires the expansion of the balloon (2) to deploy, and therefore, the tip (15) does not at all hinder the deployment of the occlusion device).

Referring to claim 92, Ryan discloses an occlusion device delivery system comprising a tubular body (3) including a distal portion (area of 3 near balloon 2), a releasably deployable occlusion device (1) positioned on the distal portion (area near 2) of the tubular body (3), the

occlusion device comprising a distal opening when deployed (end of stent 1, stent is hollow, thus has an opening) and a distal tip member (15) fixedly secured to the distal portion of the tubular body (area of 3 near 2), distal the occlusion device (see fig.3), the distal tip member (15) configured to bioabsorb or dissolve to a smaller profile when the distal tip member is placed in vivo (col.4, lines 47-59), wherein the distal tip member (15) is configured to remain fixedly secured to the distal portion of the tubular body (area of 3 near 2) during the entire bioabsorption or dissolution process (and it may not completely dissolve, in this case, would be pulled proximally through the occlusion device; col.6, lines 19-23; col.8, lines 18-27), so that the distal tip member (15) may proximally pass through the distal opening of the deployed occlusion device (1) when the tubular body is displaced in a proximal direction.

Referring to claims 68, 81, and 93, Ryan discloses the tip (15) having a guidewire lumen (perforation in distal end of capsule, col.4, lines 42-44).

Referring to claims 69, 82, and 94, Ryan discloses a solid tip (15; col.6, lines 17-19, 65-67).

Referring to claims 70-72, 83-85, and 95-96, Ryan discloses a tip (15) configured to bioabsorb or dissolve to a smaller profile in less than 15 min, preferably 5-10 min (any rate, col.6, lines 29-31, 51-53; col.7, lines 43-63).

Referring to claim 73, Ryan discloses a tip member (15), which is configured to remain disposed on the distal portion (area of 3 near 2) of the tubular body (3) during the entire bioabsorption or dissolution process (fig.3).

Referring to claims 74 and 86, Ryan discloses an occlusion device (1) comprising a distal opening (end of stent) when deployed, and the distal tip member (15), in a smaller profile (after

partial dissolution has occurred), is *configured* to proximally pass through the distal opening of the deployed occlusion device (1) when the tubular body (3) is displaced in a proximal direction (inherently some of tip 15, which is the last to dissolve, will still be present on the distal portion of the catheter, on the balloon, and on the guidewire, when the catheter is pulled back proximally at the end of the procedure, see col.6, lines 19-23; since this area contains more material to dissolve away, it will take longer, as such, tip (15), or a portion of it, which is left on the balloon, or guidewire, depending upon how long the procedure takes, is configured to be displaced proximally through the stent opening).

Referring to claims 75 and 87, Ryan discloses a tip (15) configured to bioabsorb or dissolve substantially away (col.3, lines 9-12).

Referring to claims 76, 88, and 97, Ryan discloses the tip (15) having a smooth transition at an edge of the tubular body (3), see figures 2-5.

Referring to claims 77-79, 89-91, and 98-100, Ryan discloses the occlusion device (1) to be a self-expanding stent (col.3, lines 54-67) and the tubular body (3) to be a catheter (col.3, lines 40-41).

Referring to claims 101-106, Ryan discloses a tip member (15) configured for not sliding off and staying intact during dissolution or bioabsorption (fig.3, 4).

Claims 33, 68-69, 72-82, 85-94, and 97-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (US 5,603,698, cited in previous office action). Referring to claim 33, Roberts discloses an occlusion device delivery system (2) comprising a tubular body (4) including a distal portion (10) and a distal extremity (distal end of 10-it is noted to the applicant

that portion 8 is a separate piece, made of a different material, therefore the distal extremity is interpreted by the examiner to be the far distal end of 10, proximal part 8), a releasably deployable occlusion device (14) positioned on the distal portion (10) of the tubular body (4), and a distal tip member (26) fixedly secured to the distal portion (10) of the tubular body (4), (the tip 26 **is** fixedly secured, it is mounted on the tubular body 4, and additionally held on by outer sheath 22, it is fixedly secured until removed), wherein the distal tip member (26) distally extends beyond the distal extremity (distal end of 10, proximal part 8) of the tubular body (4), the distal tip member (26) including at least a partially bioabsorbable or dissolvable material (col.6, lines 30-42).

Referring to claim 80, Roberts discloses an occlusion device delivery system (2) comprising a tubular body (4) including a distal portion (10), a releasably deployable occlusion device (14) positioned on the distal portion (10) of the tubular body (4), and a distal tip member (26) fixedly secured to the distal portion (10) of the tubular body (4), the distal tip member (26) configured to undergo bioabsorption or dissolution (col.6, lines 30-42) when the distal tip member is placed in vivo (see fig.2), wherein the distal tip member (26) is *configured* to remain fixedly secured to the distal portion (10) of the tubular body (4) during the entire bioabsorption process (tip 26 is configured to remain on the tubular body 4, and is only removed when someone forcingly removes it, even so, removal of the tip is a method step, which is irrelevant in a product claim, and Roberts discloses the same end product, a tip configured to remain on the tubular body), wherein the distal tip member (26) does not hinder deployment of the occlusion device (14) prior to undergoing bioabsorption or dissolution.

Referring to claim 92, Roberts discloses an occlusion device delivery system (2) comprising a tubular body (4) including a distal portion (10), a releasably deployable occlusion device (14) positioned on the distal portion (10) of the tubular body (4), the occlusion device (14) comprising a distal opening when deployed (fig.1a, 2), and a distal tip member (26) fixedly secured to the distal portion (10) of the tubular body (4), distal to the occlusion device (fig.1, 4), the distal tip member (26) configured to bioabsorb or dissolve to a smaller profile (fig.22f, 2g; col. 6, lines 30-42) when the distal tip member (26) is place in vivo, wherein the distal tip member (26) is *configured* to remain fixedly secured to the distal portion of the tubular body (4) during the entire bioabsorption or dissolution process, so that the distal tip member (26) may proximally pass through the distal opening of the deployed occlusion device (14) when the tubular body (4) is displaced in a proximal direction (tip 26 is configured to remain on the tubular body 4, and does dissolve to a smaller profile, fig.2g, at which time, when still on the tubular body, would be of a size capable of moving proximally through the opening in the occlusion device).

Referring to claims 68, 81, and 93, Roberts discloses the tip (26) having a guidewire lumen (35).

Referring to claims 69, 82, and 94, Roberts discloses a solid tip (fig.1).

Referring to claims 72 and 85, Roberts discloses a distal tip member (26) configured to dissolve or bioabsorb to a smaller profile (fig.2g).

Referring to claim 73, Roberts discloses a distal tip member (26) *configured* to remain disposed on the distal portion of the tubular body (4) during the entire bioabsorption or dissolution process (the tip is configured to remain there, until someone forcefully removes it,

however removal of the tip is a method step and irrelevant in a product claim. The same end product results, a tip *configured to remain disposed on the tubular body*).

Referring to claims 74 and 86, Roberts discloses an occlusion device (14) comprising a distal opening when deployed (fig.1a, 2), the distal tip member (26) in a smaller profile (for example in fig.2f, 2g), *configured* to pass through the distal opening of the deployed occlusion device (14) when the tubular body (4) is displaced in a proximal direction.

Referring to claims 75 and 87, Roberts discloses a tip (26) configured to bioabsorb or dissolve substantially away (fig.2f-2h; col.6, lines 30-43).

Referring to claims 76, 88, and 97, Roberts discloses the tip (26) having a smooth transition (28, 29) at an edge of the tubular body (4).

Referring to claims 77-79, 89-91, and 98-100, Roberts discloses the occlusion device (14) to be a self-expanding stent (col.4, lines 20-24) and the tubular body (4) to be a catheter (col.3, lines 65-67).

Referring to claims 101-106, Roberts discloses a tip member (26) which is *configured* to stay intact and not slide off during dissolution or bioabsorbtion (see arguments above).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

In the alternative to the above rejection under Roberts for the claims 33, 68-69 and 72-79, these claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,603,698, cited in previous office action). Referring to claim 33, Roberts discloses an occlusion device delivery system (2) comprising a tubular body (4) including a distal portion (10) and a distal extremity (8), a releasably deployable occlusion device (14) positioned on the distal portion (10) of the tubular body (4), and a distal tip member (26) fixedly secured to the distal portion (10) of the tubular body (4), (the tip 26 **is** fixedly secured, it is mounted on the tubular body 4, and additionally held on by outer sheath 22, it is fixedly secured until removed), the distal tip (26) including at least a partially bioabsorbable or dissolvable material (col.6, lines 30-42). Although Roberts discloses a distal tip member (26) on the distal portion (10) of the tubular body (4), Roberts does not disclose the tip (26) at the distal extremity (8) of the tubular body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the tip further distal on the tubular body, since it has been held that a mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Referring to claim 68, Roberts discloses the tip (26) having a guidewire lumen (35).

Referring to claim 69, Roberts discloses a solid tip (fig.1).

Referring to claim 72, Roberts discloses a distal tip member (26) configured to dissolve or bioabsorb to a smaller profile.

Referring to claim 73, Roberts discloses a distal tip member (26) *configured* to remain disposed on the distal portion of the tubular body (4) during the entire bioabsorption or dissolution process (the tip is configured to remain there, until someone forcefully removes it,

however removal of the tip is a method step and irrelevant in a product claim. The same end product results, a tip *configured to remain disposed on the tubular body*).

Referring to claim 74, Roberts discloses an occlusion device (14) comprising a distal opening when deployed (fig.1a, 2), the distal tip member (26) in a smaller profile (for example in fig.2f, 2g), *configured* to pass through the distal opening of the deployed occlusion device (14) when the tubular body (4) is displaced in a proximal direction.

Referring to claim 75, Roberts discloses a tip (26) configured to bioabsorb or dissolve substantially away (fig.2f-2h; col.6, lines 30-43).

Referring to claim 76, Roberts discloses the tip (26) having a smooth transition (28, 29) at an edge of the tubular body (4).

Referring to claims 77-79, Roberts discloses the occlusion device (14) to be a self-expanding stent (col.4, lines 20-24) and the tubular body (4) to be a catheter (col.3, lines 65-67).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER